UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,530	01/29/2004	Henrich Cheng	681942-1US	2231

570 7590 04/28/2010

PANITCH SCHWARZE BELISARIO & NADEL LLP
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103

EXAMINER	
MENDOZA, MICHAEL G	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
04/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@panitchlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/766,530	CHENG, HENRICH	
	Examiner	Art Unit	
	MICHAEL G. MENDOZA	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 23-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 9/25/2009 have been fully considered but they are not persuasive.

2. After further consideration the examiner will maintain the 35 USC 103(a) rejections of claims 1-21 and 23-26 over Cheng et al. in view of Schenck et al. The applicant argues that Cheng et al. fails to teach a viable/living portion of the peripheral nervous system with any portion of the central nervous system or any portion of the peripheral nervous system, and that the grafts used by Cheng et al. are not viable. The claims of the application fail to specifically claim viable/living portions of the peripheral nervous system. The claim only broadly claims the use of a portion of the peripheral nervous system. Cheng et al. teaches the use of grafts that comprises multiple intercostal nerves which are part of the peripheral nervous system. Since Cheng et al. teaches the use of at least a portion of the peripheral nervous system, the method of Cheng et al. reads on the recited claims. The application also teaches the use of a graft (non-viable) tissue which further reinforces the validity of the rejection (see claims 23-26) with Cheng et al.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. 6235041 in view of Schenck et al. 4553542.

5. As to claims 1 and 2, Cheng et al. teaches a method of functionally connecting a portion of the peripheral nervous system of a vertebrate to a potion of the central or peripheral nervous system of the vertebrate, comprising the steps of bringing potion of the peripheral nervous system and the portion of the central or peripheral nervous system close to each other, applying to the gap between the two portions a fibrin glue mixture comprising a growth factor, fibrinogen, aprotinin and divalent calcium ions so that the fibrin glue mixture (col. 6, lines 1-16) is simultaneously in contact with the two portions, and forming an attachment between the portion of the peripheral nervous system and the portion of the central or peripheral nervous system of the vertebrate (col. 1, lines 27-34). It should be not that Cheng et al. fails to teach suturing or anastomosising the two portions of the nervous system to be connected.

6. Schenck et al. teach a method for connecting portions of a nerve comprising suturing portions of a nerve together (col. 15, lines 32-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to suture two portions of the nervous system together of Cheng et al. in view of Schenck et al. for forming a strong connection to allow the glue of Cheng et al. to set and form a permanent bond.

7. As to claims 2-9, 12-19, and 23-26, Cheng/Schenck teaches the method of claim 1, wherein the growth factor is selected from the group consisting of a glial cell line-derived neurotrophic factor, transforming growth factor-beta, fibroblast growth factor,

platelet-derived growth factor, and epidermal growth factor, vascular endothelial growth factor, and neurotrophin (col. 5, lines 66-67); wherein the fibroblast growth factor is acidic fibroblast growth factor; wherein the divalent calcium ions are provided by the addition of calcium chloride or calcium carbonate; wherein the fibrin glue mixture is acidic fibroblast growth factor, fibrinogen, aprotinin and calcium chloride (col. 6, line 1-16); the step of introducing a tissue graft to the gap between the portion of the peripheral nervous system and the portion of the central nervous system; wherein tissue graft is a sural or intercostal nerve of said vertebrate (col. 7, lines 55-60).

8. As to claim 10, Cheng et al. teaches a vial B with 1 ml of aprotinin solution with 1000 KIU bovine lung aprotinin. This solution is mixed with vial D containing 2.5 ml of calcium chloride solution. Bringing the total volume of the solution of B + D to 3.5 ml. Added to the solution of C + D, dry fibrinogen between 115-232 mg in a vial A and dry thrombin between 4.9-11.1 mg in a vial C, to bring the total volume above 3.5 ml. For ease of calculation the examiner will use the solution volume of 3.5 ml. The solution of 3.5 ml with a total of 1000 KIU of aprotinin in the solution would equate to approximately 286 KIU/ml of solution. Therefor Cheng et al. reads on the limitation of the fibrin glue mixture comprises 0.0001-1000 mg/ml of fibroblast growth factor, 10-1000 mg/ml of fibrinogen, 10-500. KIU/ml of aprotinin and 1-100 mM of calcium chloride

9. As to claim 12-21, 25, and 26, the method as taught by Cheng/Schenck teaches connecting the nervous system of the vertebrate and be used to connect any portion of the nervous system of the vertebrate including the cervical root to the spinal cord.

10. As to claims 10, 11, 20, and 21, it has been held to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer,* 1962 C.C. 408. (1961).

11. As to claim 11, Cheng et al. teach a mixture comprising acidic fibroblast growth factor, fibrinogen, aprotinin and calcium chloride (col. 6, lines 1-16). It should be noted that fails to specifically disclose 1 mg/ml of fibroblast growth factor, 100 mg/ml of fibrinogen, 200 KIU/ml of aprotinin, and 8mM of calcium chloride. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed amounts, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 UPSQ 215 (CCPA 1980).

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734